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February 17, 2005

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Re:

U.S. Patent Application No.: 10/786,710

For: 7- AND 9- CARBAMATE, UREA, THIOUREA, THIOCARBAMATE, AND HETEROARYL-AMINO SUBSTITUTED TETRACYCLINE COMPOUNDS

Inventors: Nelson, Mark L., et al.

Filed: February 24, 2004 Our Ref. No.: PAZ-025CPCN

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. PTO Form SB/08;
- 3. Copies of selected references cited in PTO Form SB/08 (9); and
- 4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

February 17, 2005

Cynthia M. Scroos, Esq., Registration No. 53,623

Respectfully submitted,

LAHIME & COCKFIELD, LLP

Cynthia M. Soroos, Esq. Registration No. 53,623

Attorney for Applicants



In re the application of: Nelson, Mark L., et al.

Serial No.: 10/786,710

Filed: February 24, 2004

For: 7- AND 9- CARBAMATE, UREA, THIOUREA, THIOCARBAMATE, AND HETEROARYL-AMINO SUBSTITUTED TETRACYCLINE COMPOUNDS

Attorney Docket No.: PAZ-025CPCN

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Group Art Unit: 1626

Examiner: Not Yet Assigned

## Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on the date set forth below.

February 17, 2005

Date of Signature and of Mail Deposit

By:

Cynthia M. Soroos, Esq. Registration No. 53,623

Attorney for Applicants

## **INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. References A1-A19, B7, B10-B17, C1, C6 were previously cited and submitted to the Office in U.S. Application Serial No. 09/823,884, filed March 30, 2001 (Atty. Docket No. PAZ-025CP), of which this application is a continuation and to which this application claims priority. In accordance with 37 CFR §1.98(d), these references are not enclosed herewith, but will be provided upon request. In addition, this Information

Serial Number: 10/786,710 Page -2- Group Art Unit: 1625

Disclosure Statement presents references A20-A21, B1-B6, B8-B9, C2-C5, C7, not previously submitted to the Office, which are enclosed herewith in accordance with 37 CFR §1.97.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Cynthia M. Soroos, Esq. Registration No. 53,623 Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400

Date: <u>February 17, 2005</u>

EAH/CMS/rl Enclosures

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO 10/786,710 Application Number INFORMATION DISCLOSURE Filing Date February 24, 2004 STATEMENT BY APPLICANT First Named Inventor Nelson, Mark L. Art Unit 1626 (Use as many sheets as necessary) Examiner Name Not Yet Assigned PAZ-025CPCN 1 3 Attorney Docket Number Sheet

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	****		U.S. PA	TENT DOCUMENTS	
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Figures Appear
	A1	2,980,584	04-01-1961	Hammer	
	A2	2,990,331	06-01-1961	Neumann, et al.	
	A3	3,062,717	11-01-1992	Hammer	
	A4	3,165,531	06-01-1965	Blackwood, et al.	
	A5	3,338,963	08-01-1967	Petisi, J., et al.	
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	A8	3,557,280	01-01-1971	Weber, et al.	
	A9	3,674,859	07-01-1972	Beutel, et al.	
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	A11	4,018,889	04-19-1977	Armstrong, W.W.	
	A12	4,024,272	05-17-1977	Rogalski, W., et al.	
	A13	4,126,680	11-21-1978	Armstrong, W.W.	
	A14	5,401,729	03-28-1995	Sum, P-E, et al.	
	A15	5,532,227	07-02-1996	Golub, L.M., et al.	
	A16	5,789,395		Amin, A.R., et al.	
	A17	5,834,450	11-10-1998	Su, W.	

	FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages				
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear				
	A18	EP 536515 A1	04-14-1993	American Cyanamid Co.					
	A19	WO 94/15587 A2	07-21-1994	Kinerton Ltd.					
	A20	WO 95/21818 A1	08-17-1995	Alcon Laboratories					

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	A21	Abdelhamid, A., et al. Reactions with Hydrazonoyl Halides XIII <sup>1</sup> : Synthesis of Some New Thiadiazoline, Arylazothiazole and Pyrazole Derivatives. Phosphorous Sulfur Silicon Related Elem. 1996. 119:181-191.				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	Consider	red

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Sut	ostitute for form 1449A/B/PT	0			Complete if Known
			001 001105	Application Number	10/786,710
	NFORMATION			Filing Date	February 24, 2004
S	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Nelson, Mark L.
	(Use as many sh	eets as	s necessary)	Art Unit	1626
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	PAZ-025CPCN

			U.S. PA	TENT DOCUMENTS	
Examiner	C:4-	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	Cite No. <sup>1</sup>	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	B1	2003/0125348 A1	07-03-2003	Nelson, et al.	
	B2	6,617,318 B1	09-09-2003	Nelson, et al.	
	B3	6,624,168 B2	09-23-2003	Nelson, et al.	
	B4	6,642,270 B2	11-04-2003	Nelson, et al.	
	B5	6,683,068 B2	01-27-2004	Nelson, et al.	
	B6	6,818,635 B2	11-16-2004	Nelson, et al.	

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵			
	B7	WO 96/34852 A1	11-07-1996	Pfizer, Inc.		Н			
	B8	JP 09-025273	01-28-1997	Nitto Chem Co.					
	B9	JP 09-169748	06-30-1997	Kuraray Co. Ltd.					
	B10	WO 98/19693 A1	05-14-1998	Trega Biosciences, Inc.					
	B11	WO 99/37306 A1	07-29-1999	Tufts University					

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		NON PATENT LITERATURE DOCUMENTS	
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	B12	Albar, H.A., et al. "Synthesis of Novel Spiro and Fused Cyclopenta[c]-pyrazole and -pyrimidine Derivatives." J. Chem. Research. 1997; 40-41.	
	B13	Barden, T.C., et al. "Glycylcyclines. 3. 9-Aminodoxycyclinecarboxamides." J Med Chem. 1994 Sep 30; 37(20):3205-11.	
	B14	Berge, S.M., et al. "Pharmaceutical salts." J Pharm Sci. 1977 Jan; 66(1):1-19.	
	B15	Beyer, L., et al. "Synthesis and Characterization of Thiourea Derivatives of ∝-Aminoacids. Crystal Structure of Methyl L-valinate and L-leucinate Derivatives." <i>Tetrahedron.</i> 1996; 52(17):6233-40.	
	B16	Fikry, R.M. "Synthesis of some New Pyrimidine and Condensed Pyrimidine Derivatives." <i>J. Indian. Chem.</i> Soc. 1996 Dec; 73:698-9.	
	B17	Kassem, E.M., et al. "Synthesis of New Benzothiazole-2-Acrylic Acid Derivatives." Pak. J. Sci. Ind. Res. 1995 Dec; 38(11-12):424-7.	
		Ind. Res. 1995 Dec; 38(11-12):424-7.	l

Examiner Date Signature Considered		
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	Signature	Considered

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Sub	estitute for form 1449A/B/PT	<u>o</u>		Complete if Known			
			Application Number	10/786,710			
			<del>-</del>	Filing Date	February 24, 2004		
S	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Nelson, Mark L.		
	(Use as many she	ets as	necessary)	Art Unit	1626		
			:	Examiner Name	Not Yet Assigned		
Sheet	3	of	3	Attorney Docket Number	PAZ-025CPCN		

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	C1	Nassar, S.A., et al. "Synthesis and Characterization of Some Biologically Active Pyrimidine Derivatives Containing Sulphur." 1997; 40(3):239-47.	
	C2	Omar, et al. Synthesis of Some Novel Benzimidazole Derivativses as Antimicrobial Agents J. Pharm. Sci. Egypt. 1996. 37(1-6):609-620.	
	C3	Sharaf El-Din, et al. New Pyridazinedione Derivatives: Synthesis and Antimicrobial Activity. Alexandria J. Pharm. Sci. 1997. 11(1):9-12.	
	C4	Tomchin, et al. Thiourea and Thiosemicarbazide Derivatives: Structure, Transformations, and Pharmacological Activity. Part II. Antihypoxic Activity of 1,2,4-Triazino[5,6-b]indole Derivatives. Khim. –Farm. Zh. 1997. 31(3):125-127.	
	C5	Tomchin, et al. Thiourea and Thiosemicarbazide Derivatives: Structure, Transformations, and Pharmacological Activity. Part V. Antihypoxic and Actoprotector Activity of Imidazo (4,5-b)indole Derivatives. Khim. –Farm. Zh. 1998. 32(2):59-63.	
	C6	Van den Bogert, C., et al. "Doxycycline in combination chemotherapy of a rat leukemia." Cancer Res. 1988 Dec 1; 48(23):6686-90.	
	C7	Zhu, et al. Synthesis and Nitration of Bicyclic Thiourea Derivatives. Hanneng Cailiao. 1997. 5(4):165-170.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Signature	Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.